

The presentation will begin shortly. There will be no audio until then.



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Overview of Recent ACIP Recommendations

Abbi Berg, MPH  
Vaccines for Children Manager



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Recent Recommendations

~ February 2015

- . Influenza
- . Meningococcal B
- . HPV9
- . Yellow Fever

~ August 2014

- . PCV13 in adults



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## Influenza – discussion of LAIV preference




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### Removal of LAIV Preference

- “ For the 2015 – 2016 influenza vaccination season, the ACIP removed the preference for live attenuated influenza vaccine (LAIV) over inactivated influenza vaccine (IIV) for children ages 2 – 8 years. Either vaccine may be used.
- . For the 2014-2015 season a preference for LAIV was expressed by the ACIP for healthy children.
- . Exact rationale behind removing the preference is unknown but may be related to LAIV’s estimated lower effectiveness against H1N1 strain.




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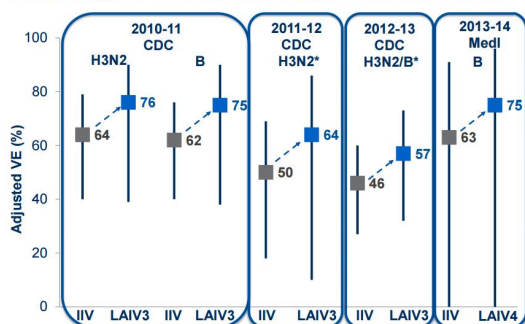
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Taken from MedImmune Presentation for ACIP Meeting  
**US VE Against H3N2 and B in Children 2-8 Years**



Data for children 2-8 years of age. Adjusted VE estimates are not controlled for differences between LAIV and IIV recipients. Studies did not have sufficient statistical power to demonstrate superiority.  
\*H3N2 was predominant in 2011-12; H1N1/pdm09 and B strains also co-circulated. In 2012-13 H3N2 was predominant early in the season and B was predominant late in the season.

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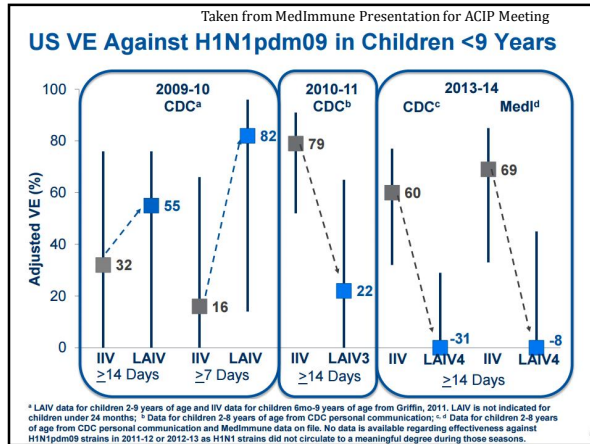
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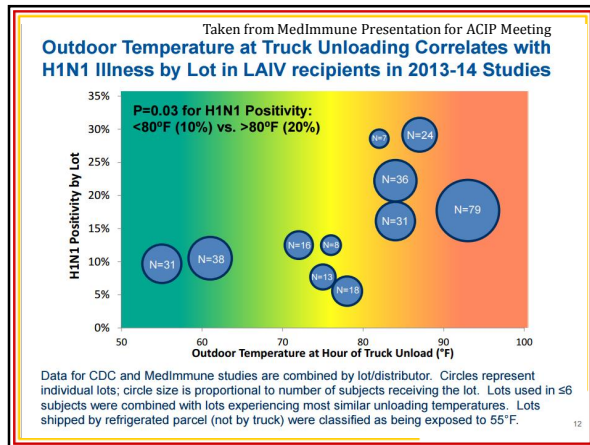
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## Updated Language

“ For healthy children aged 2 through 8 years who have no contraindications or precautions, either LAIV or IIV is an appropriate option. No preference is expressed for LAIV or IIV for any person aged 2 through 49 years for whom either vaccine is appropriate. An age appropriate formulation of vaccine should be used.

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## Influenza Vaccine Schedule

- ~ The recommendations for the 2015- 2016 influenza vaccine season will be made at the June ACIP meeting.
- . The immunization program will send out those recommendations when they are available.




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## Meningococcal B Vaccine




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## Current Meningococcal Vaccines Used

- ~ All are protective against invasive meningococcal disease caused by *Neisseria meningitidis* types A, C, Y, and W-135
- . Conjugate vaccines
  - ~ Menactra, for ages 9 months – 55 years
  - ~ Menveo, for ages 2 months -55 years for routine use
- . Polysaccharide vaccine
  - ~ Menomune, for ages 2 and up
    - . Not recommended for routine vaccination because of its relative ineffectiveness in infants and its relatively short duration of protection




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### Current MenACWY Conjugate Vaccine Recommendations for Persons at Increased Risk

“ Routine vaccination of persons aged  $\geq 2$  months at increased risk for meningococcal disease, including:

- . Persons with persistent complement component deficiencies
- . Persons with anatomic or functional asplenia
- . Microbiologists who are exposed routinely to isolates of *Neisseria meningitidis*




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### Current MenACWY Recommendations, cont.

- . Persons at risk during a community outbreak attributable to a vaccine serogroup
- . Persons who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic
- . Unvaccinated or incompletely vaccinated first-year college students living in residence halls
- . Military recruits




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### Two Mening B Vaccines

“ Trumenba® (Pfizer)

- . 3-dose series (0, 2, 6 months)
- . Licensed in the U.S. on October 29, 2014

“ Bexsero® (Novartis)

- . 2-dose series (0, 1–6 months)
- . Licensed in the U.S. on January 23, 2015

“ The same vaccine product should be used for the entire series.




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### Age Limit

- " Both vaccine products are licensed for ages 10 – 25.
- " ACIP recommended either vaccine for people age 10 and older (no maximum age limit – off label).




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### Current High Risk Mening B Recommendations

- " "High-risk" includes functional or anatomic asplenia, persistent complement component deficiencies, meningococcal B outbreak settings, and microbiologists. (same as 4-valent meningococcal conjugate vaccine - MCV4)
  - . In order for it to be considered an outbreak of meningococcal B, three or more cases of the same serotype must occur within three months of each other.




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### Meningococcal B Outbreaks in US

- " Princeton University
  - . Eight confirmed cases and one outbreak-associated case in another university were reported.
  - . More than 13,000 doses of mening B vaccine were administered under FDA investigational new drug application as mening B vaccine was not yet licensed in US.
- " University of California, Santa Barbara
  - . Four confirmed cases
  - . More than 17,000 doses of mening B vaccine were administered under FDA investigational new drug application as mening B vaccine was not yet licensed in US.




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## Future Recommendations

- " The high-risk recommendation currently does not include international travel, college students, or military. (different from MCV4 recommendation)
- " The ACIP will discuss additional recommendations (college and routine adolescent) for meningococcal B vaccine at their June 2015 meeting.
  - " NDDoH will send out any updates to mening B vaccine recommendations.




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## Vaccine Availability

- " Meningococcal B vaccines will be available to order for Vaccines for Children (VFC) eligible children around the first week of May.
  - " Providers will be notified by email when this vaccine is available for order from the North Dakota Department of Health (NDDoH).
- " Both brands of meningococcal B vaccine are currently available for purchase in the private market.
- " Mening B vaccines have been added to NDIIS so they can be entered into patient immunization records.




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## Case Study

Wyatt is an 18 year old high school student who is college bound. He has received MCV4 when he was 12 and 16 years of age. What should Wyatt receive before going away to college?




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### 18 Year Old College Student

- " A) Mening B vaccine is not currently routinely recommended to be given to healthy college students.
- " B) Wyatt should receive one booster dose of MCV4 prior to college entry.
- " C) Wyatt should receive one dose of Mening B vaccine.
- " D) Wyatt should receive two or three doses of Mening B vaccine depending on the brand of vaccine administered.



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### Correct Answer

- " A) Mening B vaccine is not currently routinely recommended to be given to healthy college students.
- " B) Wyatt should receive one booster dose of MCV4 prior to college entry.
- " C) Wyatt should receive one dose of Mening B vaccine.
- " D) Wyatt should receive two or three doses of Mening B vaccine depending on the brand of vaccine administered.



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### HPV9 Vaccine



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### HPV Vaccine Options

	Bivalent (Cervarix®)	Quadrivalent (Gardasil®)	9-Valent (Gardasil 9®)
Manufacturer	GlaxoSmithKline	Merck	Merck
Strains Protected Against	16, 18	6, 11, 16, 18	6, 11, 16, 18, 31, 33, 45, 52, 58
Licensed	Females 9 – 25 yrs	Females 9 – 26 yrs Males 9 – 26 yrs	Females 9 – 26 yrs Males 9 – 15 yrs




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### Additional Protection from HPV9

- “ HPV2, HPV4 and HPV9 all protect against HPV 16 and 18, types that cause about 66% of cervical cancers and the majority of other HPV-attributable cancers in the United States.
- “ HPV9 targets five additional cancer causing types, which account for about 15% of cervical cancers. HPV4 and HPV9 also protect against HPV 6 and 11, types that cause genital warts.




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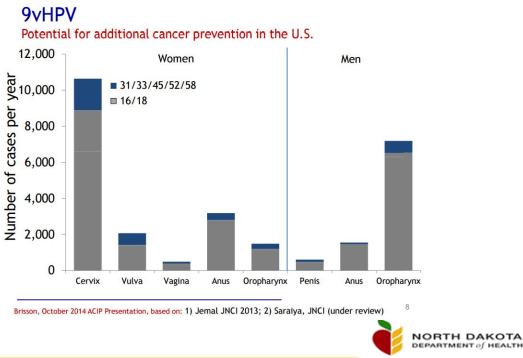
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### Additional Cancer Prevention




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### HPV9 Safety Summary

- " Generally well tolerated in >15,000 recipients
- " Adverse event profile similar to 4vHPV across age, gender, race, ethnicity
- " More injection site-related swelling and erythema in females who received 9vHPV (most mild/moderate in intensity)
- " Lower frequency of adverse events in males compared to females (similar to 4vHPV)




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### HPV9 Vaccine Recommendations

- " ACIP recommends routine HPV vaccination at age 11 or 12 years.
  - . The vaccination series can be started beginning at age 9 years.
  - . Vaccination is also recommended for females ages 13 through 26 years and for males ages 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series.
  - . Males ages 22 through 26 years may be vaccinated.
    - " Recommendation for men who have sex with men and for immunocompromised persons (including those with HIV infection).




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### HPV9 Vaccines Recs, cont.

- " The schedule for vaccination is the same – three dose schedule at 0, 1-2 , and 6 months.
  - . The ACIP did not discuss a two-dose HPV schedule. The two-dose HPV vaccination schedule will most likely not be discussed by ACIP until 2016.
  - " NDDoH will send out any HPV9 vaccine updates when they are available.




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### HPV9 Vaccine Recommendations, cont.

- " Vaccination of females is recommended with HPV2, HPV4 (as long as this formulation is available), or HPV9.
- " Vaccination of males is recommended with HPV4 (as long as this formulation is available) or HPV9.
  - . Off label use of HPV9 for males 16-26.




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### HPV9 Vaccine Recommendations, cont.

- " ACIP did not express a preference for HPV9 vaccine over other HPV vaccines. HPV9 was recommended as an option for HPV vaccination. Providers may use HPV2, HPV4 (as long as available), or HPV9.
- " If vaccination providers do not know or do not have available the HPV vaccine product previously administered, or are in settings transitioning to HPV9, for protection against HPV 16 and 18, any HPV vaccine product may be used to continue or complete the series for females. HPV4 or HPV9 may be used to continue or complete the series for males.




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### HPV9 Vaccine Recs, cont.

- " **HPV9 vaccination of persons who previously received 3 doses of HPV4 or HPV2 is not a routine recommendation at this time.**
- " Available data demonstrate no safety concerns in persons who are vaccinated with HPV9 after having been vaccinated with HPV4.




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### HPV9 Vaccine Recs, cont.

- “ The incremental benefit of vaccination of HPV9 after a series of HPV4 would be small and mainly for females. The only data available are for HPV9 vaccination of females after a complete 3-dose HPV4 series and with the first dose of HPV9 given at least 12 months after completing the HPV4 series.



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### Vaccine Availability

- “ HPV9 Vaccine is available on the private market now.
- “ HPV9 vaccine will be available from NDDoH in the very near future.
  - . Early May.
- “ Until then vaccine orders for HPV4 may be cut so that providers are not left with large stocks of HPV4 vaccine when HPV9 becomes available.



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### Case Study

Michael is a 20 year old male who has an appointment today. He has never received HPV vaccine before. Should he receive HPV4, HPV9 or HPV2 vaccine today?



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### 20 Year Old Male

- " A) **HPV9 or HPV4**. Males can receive either.
- " B) **HPV4**. HPV9 is not licensed for males over 15 years of age.
- " C) **HPV2**. This is considered the "male" HPV vaccine as it only protects against anogenital warts.
- " D) **Neither**. A 20 year old male without high risk conditions is not routinely recommended to receive HPV vaccine.




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### Correct Answer

- " A) **HPV9 or HPV4**. Males can receive either.
- " B) **HPV4**. HPV9 is not licensed for males over 15 years of age.
- " C) **HPV2**. This is considered the "male" HPV vaccine as it only protects against anogenital warts.
- " D) **Neither**. A 20 year old male without high risk conditions is not routinely recommended to receive HPV vaccine.




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### Case Study

Carly is a 16 year old female who has completed her HPV series with HPV4 vaccine and is being seen today. She would like to know if she should complete a series of HPV9 vaccine.




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### 16 Year Old Female

- " A) Carly should **complete the HPV9 series** following the same schedule of 0, 1-2, and 6 months.
- " B) Carly should only receive **a one-time booster** dose of HPV9.
- " C) **No further doses needed.** At this time there is not a recommendation for HPV9 after a complete series of HPV4 vaccine.
- " D) Only **repeat the series** if she has a high risk condition.



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### Correct Answer

- " A) Carly should **complete the HPV9 series** following the same schedule of 0, 1-2, and 6 months.
- " B) Carly should only receive **a one-time booster** dose of HPV9.
- " **C) No further doses needed.** At this time there is not a recommendation for HPV9 after a complete series of HPV4 vaccine.
- " D) Only **repeat the series** if she has a high risk condition.



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### Case Study

Rebecca is a 12 year old female who is at your clinic today to get her 7<sup>th</sup> grade immunizations. Your clinic does not have HPV9 vaccine yet?  
What should she get today?



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### 12 Year Old

- " A) Tell her to come back in a few months when HPV9 is available.
- " B) Vaccinate her today with HPV4 vaccine.
- " C) Delay HPV vaccine until she is older.
- " D) Refer her to a facility who has HPV9 vaccine.



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### Correct Answer

- " A) Tell her to come back in a few months when HPV9 is available.
- " B) Vaccinate her today with HPV4 vaccine.
- " C) Delay HPV vaccine until she is older.
- " D) Refer her to a facility who has HPV9 vaccine.



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### Yellow Fever Vaccine



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### Updated Booster Recommendations

- " Single dose of YF vaccine provides long-lasting protection in most travelers.
- " No longer recommend booster doses of YF vaccine for **most** travelers.
- " Recommend YF vaccine booster doses for persons who immune response to previous dose might have been compromised.
- " Consider YF vaccine booster doses for persons in higher-risk setting for exposure to YF virus.




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### Yellow Fever Vaccine Recs, cont.

- " Recommendation for certain populations "Additional doses of yellow fever vaccine are recommended for certain travelers, including:
  - . Women pregnant when they received their initial dose of yellow fever vaccine should receive one additional dose of yellow fever vaccine prior to their next travel.
  - . Individuals who received a hematopoietic stem cell transplant after receiving a dose of YF vaccine and who are sufficiently immunocompetent to be safely vaccinated should be revaccinated prior to their next travel that puts them at risk for yellow fever virus infection.
  - . Individuals who were HIV-infected when they received their last dose of yellow fever vaccine should receive a dose every 10 years if they continue to be at risk for yellow fever virus infection
- " Persons being considered for additional doses of yellow fever vaccine should be assessed for contraindications or precautions.




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### High Risk Setting Recommendations

- " A booster dose may be considered for travelers who received their last dose of YF vaccine at least 10 years previously and who will be in a higher-risk setting based on season, location, activities, and duration of their travel. This would include travelers who plan to spend a prolonged period of time in endemic areas or those traveling to highly endemic areas such as rural West Africa during peak transmission season or areas with ongoing outbreaks.




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### Laboratory Workers

“ Laboratory workers who routinely handle wild-type yellow fever virus should have yellow fever virus specific neutralizing antibody titers measured at least every 10 years to determine if they should receive additional doses of the vaccine. For laboratory workers who are unable to have neutralizing antibody titers measured, yellow fever vaccine should be given every 10 years as long as they remain at risk.



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### Yellow Fever Vaccine Recs, cont.

- “ NDDoH will send out any clarifications or future recommendations when they become available.
- “ To become certified to order and administer yellow fever vaccine please contact NDDoH.
  - . 701.328.3386 or toll-free 800.472.2180.



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### PCV13 Vaccine for Adults



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## Pneumococcal Vaccines

### " PPSV23

- . Pneumovax®
- . Routinely given to adults over 65 years of age and adults 19-64 years who have chronic health issues or conditions that put them at higher risk of serious infection (later slide).
- . Protects against 23 different pneumococcal strains.
- . Polysaccharide vaccine



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## Pneumococcal Vaccines, cont.

### " PCV13

- . Prevnar®
- . Routinely recommended for children.
- . New recommendation for routine vaccination of adults over 65 years.
- . Protects against 13 strains of pneumococcal disease.
- . Conjugate vaccine



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## Conjugate vs Polysaccharide

### " Polysaccharide Vaccine

- . Slightly older vaccine technology
- . Have protected many adults in the past and still continues to do so
- . Definite drawbacks:
  - ~ Little or short-lived impact on carriage of bacteria
  - ~ Decreased immune response after repeated doses
    - . Removal of revaccination every 5 years in adults
  - ~ Limited ability to protect children under two years of age



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## Conjugate vs. Polysaccharide, cont.

### ~ Conjugate Vaccines

- . Newer vaccine technology
- . Have also seen move from polysaccharide to conjugate in meningococcal vaccines
- . Several advantages:
  - ~ Ongoing protection against bacteria
  - ~ Reduction in carriage of bacteria
  - ~ Offers protective immune response in infants
  - ~ Less likely to have diminished immune response with repeated doses



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## Two Adult PCV13 Recommendations

- 1) High Risk Adults 19-64
- 2) Routine Recommendation for All Adults over 65 Years of Age



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## High Risk Adult PCV13 Recommendations

- ~ Expanded to include adults 19 years or older with **specific immunocompromising conditions**
  - . (see next slide)
- ~ To be used in conjunction with PPSV23 to prevent severe or fatal pneumococcus infection
  - . These high risk patients can be more than 20 times more likely than healthy adults to be infected



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### Adult PCV13 Recommendations Cont.

The CDC recommends the use of PCV13 in adults 19 years of age or older with specific immunocompromising conditions.

Risk Group	Underlying Medical Condition	PCV13	PPSV23*	Revaccination at 5 years after first dose
		Recommended	Recommended	
Immunocompetent persons	Chronic heart disease <sup>1</sup>		✓	
	Chronic lung disease <sup>2</sup>		✓	
	Diabetes mellitus		✓	
	CSF leaks	✓	✓	
	Cochlear implants	✓	✓	
	Alcoholism		✓	
	Chronic liver disease		✓	
	Cigarette smoking		✓	




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Risk Group	Underlying Medical Condition	PCV13	PPSV23*	Revaccination at 5 years after first dose
		Recommended	Recommended	
Persons with functional or anatomic asplenia	Sickle cell disease/other hemoglobinopathies	✓	✓	✓
	Congenital or acquired asplenia	✓	✓	✓
Immunocompromised persons	Congenital or acquired immunodeficiencies <sup>3</sup>	✓	✓	✓
	HIV infection	✓	✓	✓
	Chronic renal failure	✓	✓	✓
	Nephrotic syndrome	✓	✓	✓
	Leukemia	✓	✓	✓
	Lymphoma	✓	✓	✓
	Hodgkin disease	✓	✓	✓
	Generalized malignancy	✓	✓	✓
	Iatrogenic immunosuppression <sup>4</sup>	✓	✓	✓
	Solid organ transplant	✓	✓	✓
	Multiple myeloma	✓	✓	✓




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### PCV13 Adult Recommendations For 65 and Older

- ” On August 13, 2014 the ACIP voted to recommend one dose of PCV13 to every adult 65 and older who has not had one previously.
- . PCV13 should be given in addition to PPSV23 after the patient turns 65 years of age. The two doses should be separated by at least 6 months.




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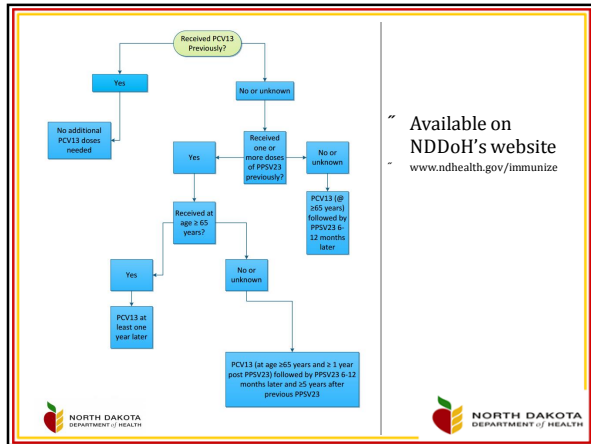
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### Pneumococcal Naive

“ Adults 65 and older who have not had a dose of PPSV23 (Pneumovax®) or whose history is unknown should receive a dose of PCV13 followed at least 6 - 12 months later by a dose of PPSV23.

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### Previously Received PPSV23

“ Adults 65 and older who have not had a dose of PCV13, but have already received a dose of PPSV23 since turning 65 should receive a dose of PCV13 at least 1 year after the dose of PPSV23.

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## Previously Received PPSV23 Before 65 Years of Age

- “ Adults 65 and older who received a dose of PPSV23 before turning 65 should have a dose of PCV13 at least 1 year after the most recent dose of PPSV23, followed by a dose of PPSV23 at least 6-12 months later, provided that the minimum interval between the 2 doses of PPSV23 is at least 5 years.




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## Medicare Part B Coverage

- “ Medicare Part B has updated its coverage for pneumococcal vaccine to comply with the new Advisory Committee on Immunization Practices (ACIP) recommendations.
- “ Effective on or after September 19, 2014, Medicare Part B will cover:
  - . An initial pneumococcal vaccine to all Medicare beneficiaries who have never received the vaccine under Medicare Part B; **and**
  - . A different, second pneumococcal vaccine one year after the first vaccine was administered (that is, 11 full months have passed following the month in which the last pneumococcal vaccine was administered).
- “ For more information and additional guidance, please see the attached documents or visit <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R3159CP.html>.




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## Case Study

66 year old Judy received a PPSV23 on her 65<sup>th</sup> birthday. What should she receive today? She has no other history of pneumococcal vaccine.




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### 66 Year Old, PPSV23 when she was 65 years old

- " A) Receive a second dose of PPSV23.
- " B) Receive a dose of PCV13 since it has been longer than six months since her dose of PPSV23.
- " C) Judy should receive a dose of PPSV23 but it cannot be given until she is 70 so there are five years in between doses of PPSV23.
- " D) Judy needs no further doses of pneumococcal vaccine.




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### Correct Answer

- " A) Receive a second dose of PPSV23.
- " B) Receive a dose of PCV13 since it has been longer than six months since her dose of PPSV23.
- " C) Judy should receive a dose of PPSV23 but it cannot be given until she is 70 so there are five years in between doses of PPSV23.
- " D) Judy needs no further doses of pneumococcal vaccine.




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### Case Study

70 year old Sheldon received a PPSV23 when he was 55 because he is a heavy smoker. He hasn't had any doses since. How many doses of pneumococcal vaccine and what brand does he need?




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**70 Year Old with PPSV23 at 55  
Years Old**

- " A) A PPSV23 only to complete his series.
- " B) A PCV13 now and again in five years.
- " C) A PCV13 now and a PPSV23 6-12 months later.
- " D) No further pneumococcal doses necessary.



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**Correct Answer**

- " A) A PPSV23 only to complete his series.
- " B) A PCV13 now and again in five years.
- " C) A PCV13 now and a PPSV23 6-12 months later.
- " D) No further pneumococcal doses necessary.



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**Case Study**

Candace is a 65 year old diabetic patient who got her PPSV23 two years ago with her flu shot. What should she receive now, if anything? Does she need another PPSV23?



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### 65 Year Old with a PSPV23 at 63 Years Old

- " A) A PCV13 with a PPSV23 6-12 months later.
- " B) A PCV13 with a PPSV23 five years after the original PPSV23 (68 years old).
- " C) Two additional PPSV23s separated by five years.
- " D) No further doses necessary.




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### Correct Answer

- " A) A PCV13 with a PPSV23 6-12 months later.
- " B) A PCV13 with a PPSV23 five years after the original PPSV23 (68 years old).
- " C) Two additional PPSV23s separated by five years.
- " D) No further doses necessary.




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### Type your question in the chat window to the right

After the presentation, questions may be sent to:

Molly Howell	mahowell@nd.gov
Abbi Berg	alberg@nd.gov
Amy Schwartz	amschwartz@nd.gov
Miranda Baumgartner	mlbaumgartner@nd.gov
Sherrie Meixner	smeixner@nd.gov
Mary Woinarowicz	mary.woinarowicz@nd.gov
Dominick Fitzsimmons	dfitzsimmons@nd.gov

**Immunization Program :**  
701.328.3386 or toll-free 800.472.2180




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## Post-test

### ~ Post-test

- . Nurses interested in continuing education credit, visit:

<http://www.ndhealth.gov/disease/post/default.aspx?PostID=77>

- . Successfully complete the four-question post-test to receive your certificate.

### ~ Credit for this session is available until Tuesday, May 12<sup>th</sup> 2015.

### ~ This presentation will be posted to our website: [www.ndhealth.gov/immunize](http://www.ndhealth.gov/immunize).



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